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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,838	11/03/2003	David Fikstad	01235-23625	5766

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,838	FIKSTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,48-52,54-61,65 and 72-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,48-52,54-61,65 and 72-82* is/are rejected.

7)☒ Claim(s) *35 and 59-60* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 35, 48-52, 54-61, 65 and 72-82 are presented for examination.

Applicant's Amendment, Terminal Disclaimers and Declaration under 37 C.F.R. 1.132 of Chandrashekar Giliyar filed November 7, 2007 have each been received and entered into the present application.

Claims 35, 48-52, 54-61, 65 and 72-82 remain pending and under examination. Claims 42-47 and 66-71 are cancelled and claims 35, 48, 59-60 and 72 are amended.

In view of the acceptable nature of the Terminal Disclaimer filed November 7, 2007, the obviousness-type double patenting rejections over claims 1, 16-19, 21, 24, 32-33 and 37-43 of copending U.S. Patent Application No. 10/764,016 or claims 1, 3-31 and 33-34 of copending U.S. Patent Application No. 11/122,788 are hereby **withdrawn**.

Applicant's arguments, filed November 7, 2007, and amendments to the claims have been fully considered. Rejections and objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and objections are either reiterated or newly applied. They constitute the complete set of rejections and objections presently being applied to the instant application.

Objection to the Claims (New Grounds of Objection)

Claims 35 and 59-60 are objected to for misspelling the word ---polyethyleneglycol--- as "polethyleneglcyol" in line 19 of claim 35 and line 17 of either claim 59 or 60.

Claim Rejections - 35 USC § 101 (New Grounds of Rejection)

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35, 48-52, 54-61, 65 and 72-82 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Present claim 35, and the claims dependent therefrom, reads upon a pharmaceutical composition comprising a therapeutically effective amount of cilostazol; a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, etc. (claim 35, l. 3-11); and a release modulator which synchronizes the release of the drug and the solubilizer selected from the group consisting of methyl cellulose, a hydroxypropylmethylcellulose derivative, etc. (claim 35, l.12-18), wherein the cilostazol is released over an extended period of time.

Present claim 59 is directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to an oral dosage form thereof.

Present claim 60 is also directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to a solid oral dosage form thereof.

Instant claims 35 and 59-60, and the claims dependent therefrom, are directed to non-statutory subject matter because it is unclear whether the claims are intended to encompass a product or a process. Specifically, claims 35 and 59-60 recite limitations clearly directed to a product, i.e., a pharmaceutical composition or oral dosage form or solid oral dosage form comprising a therapeutically effective amount of cilostazol and a solubilizer and a release modulator which synchronizes the release of the cilostazol and the solubilizer, but then goes on to state limitations that are clearly directed to a process, i.e., the cilostazol is released over an extended period of time. Accordingly, it is unclear whether Applicant intends to claim a product or process. The overlap between these two statutory categories of invention (i.e., product and process) renders the subject matter of instant claims 35 and 59-60 (as well as dependent claims 48-52, 54-58, 61, 65 and 72-82 because they do not correct this deficiency in independent claims 35 and 59-60) non-statutory under 35 U.S.C. 101 because 35 U.S.C. 101 is drafted in a manner so as to

set forth the statutory classes of invention *in the alternative only*. Please see *Ex parte Lyell*, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) Id. at 1551.

To overcome the instant rejection, it is suggested to Applicant to reword the claims to recite the release properties as a characteristic or a capability of the claimed product. Note that this is a suggestion to overcome the present rejection under 35 U.S.C. 101 and that the adoption of such a suggestion does not necessarily equate to the obviation of any other rejection set forth in the instant Office Action.

This rejection is necessitated by Applicant's amendments to the claims because the present amendment to independent claims 35 and 59-60 now presents the release of the cilostazol over an extended period of time as an active step of the claimed products (i.e., by use of the language "is released"), whereas the previously pending claims recited this limitation as a property or characteristic of the claimed product (i.e., that the release modulator of the claimed composition or dosage form functioned to synchronize release of the cilostazol and the solubilizer). This newly amended active step of release is tantamount to a process limitation rather than simply a property or capability of the claimed composition and, thus, renders the instantly amended claims non-statutory pursuant to the provisions of 35 U.S.C. 101 as discussed *supra*.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 48-52, 54-61, 65 and 72-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 35 reads upon a pharmaceutical composition comprising a therapeutically effective amount of cilostazol; a solubilizer selected from the group consisting of polyoxyl 40 castor oil, polyoxyl 35 castor oil, etc. (claim 35, l. 3-11); and a release modulator which synchronizes the release of the drug and the solubilizer selected from the group consisting of a hydroxypropylmethylcellulose derivative, glycerol monostearate, methyl cellulose, etc. (claim 35, l.12-18), wherein the cilostazol is from 0.5-50% w/w of the composition and at least 95wt% of the cilostazol is suspended in the composition, the solubilizer is present from 15-95% w/w of the composition, the release modulator is from 1-50% w/w of the composition, and wherein the cilostazol is released over an extended period of time.

Present claim 59 is directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to an oral dosage form thereof.

Present claim 60 is also directed to substantially identical subject matter as present claim 35, but for the fact that it is specifically directed to a solid oral dosage form thereof.

In particular, the specification and claims as originally filed fail to provide adequate written description for (1) a hydroxypropylmethylcellulose derivative as the release modulator (claim 35, 59 or 60); (2) glycerol monostearate as the release modulator (claim 35, 59 or 60); (3) at least 95 wt% of the cilostazol suspended in the composition (claim 35, 59 or 60).

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Regarding Applicant's limitations directed to (1) "a hydroxypropyl methylcellulose derivative" or (2) "glycerol monostearate" as the release modulator of the claimed composition (claims 35, 59 or 60), Applicant discloses various release modulators for use in the claimed composition at pages 14-15 of the instant specification, stating that: "The pharmaceutical compositions of the present invention also include a release modulator that synchronizes the release of the drug and the solubilizer over an extended period of time...Specific examples of polymeric materials include, without limitation, high molecular weight polyethylene glycol, cellulosics, (*e.g.,* ethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose (HPMC), hydroxypropyl methyl cellulose phthalate (HPMCP), hydroxypropyl methylcellulose succinate (HPMCS), cellulose acetate...Specific examples of fatty acids of fatty alcohols and derivatives useful as release modulators include, but are not limited to...glycerol distearate, glycerol dipalmitate, glycerol palmitostearate...or cetyl ester wax."

However, such disclosure of "hydroxypropyl methylcellulose", "hydroxypropyl methycellulose phthalate" or "hydroxypropyl methylcellulose succinate" is not adequate written support to now broaden the claim(s) to read upon the use of any hydroxypropyl methylcellulose derivative *per se* when such a

genus was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the use of "hydroxypropyl methylcellulose derivatives" *per se* as the release modulator component of the claimed pharmaceutical composition or dosage form(s) thereof, but rather was solely in possession of the concept of the use of hydroxypropyl methyl cellulose, hydroxypropyl methylcellulose phthalate or hydroxypropyl methylcellulose succinate as the release modulator component of the claimed pharmaceutical composition or dosage form(s) thereof.

Furthermore, the disclosure of various glycerol compounds, such as, e.g., glycerol distearate, glycerol dipalmitate, etc., is also not adequate written support to now broaden the claim(s) to read upon the use of glycerol monostearate when such a compound was neither disclosed in the specification nor the claims as originally filed. This is a broadening of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure. It is clear, therefore, that Applicant was not in possession of the concept of the use of "glycerol monostearate" as the release modulator component of the claimed pharmaceutical composition or dosage form(s) thereof, but rather was solely in possession of the concept of the use of other glycerol compound, e.g., glycerol distearate, etc. as the release modulator component of the claimed pharmaceutical composition or dosage form(s) thereof.

Regarding Applicant's limitation directed to (3) at least 95 wt% of the cilostazol suspended in the composition, Applicant relies upon Example 2 and the data demonstrated in the Declaration of Chandrashekar Giliyar under 37 C.F.R. 1.132 in support of this limitation. The Examples presented in the Declaration of Chandrashekar Giliyar are directed to three discrete combinations of agents, i.e., 400 mg cilostazol/10 mg TPGS; 400 mg cilostazol/10 mg TPGS:TS mixture (7.2:1 ratio by weight); and 400 mg cilostazol/10 mg TPGS:GMS mixture (7.2:1 ratio by weight), wherein "TPGS" is d-alpha-tocopheryl

polyethylene glycol succinate, "TS" is d-alpha-tocopheryl succinate, and "GMS" is glyceryl monostearate. HPLC was used to determine the solubility of cilostazol in the components, which was 5.4±1.4 mg/g TPGS; 4.0±0.9 mg/g TPGS:TS; and 4.2±-0.6 mg/g TPGS/GMS, respectively. Dr. Giliyar concludes that the solubility of cilostazol in the different inactive component/solubilizers at about 75°C is only about 0.5% w/w, which indicates that "at least 95 wt% of the cilostazol present would be in suspended form" and also indicates that "the solubility of cilostazol in the same compositions at room temperature is likely to be even lower" (p.3, Declaration). Dr. Giliyar states that the compositions exemplified in the Declaration are in accordance with those described in Example 2 of the instant specification.

While such testing and results have been fully and carefully considered, the exemplified compositions are directed to very specific mixtures of cilostazol and release modulator/solubilizer combinations in particular amounts and/or particular ratios (where a mixture of solubilizing components were used, i.e., TPGS:TS and TPGS:GMS mixtures, a ratio of 7.2:1 by weight was used) under specific conditions (i.e., 75°C). Such disclosure fails to be supportive of the concept that at least 95 wt% cilostazol is inherently suspended in the composition using *any* claimed release modulator and/or solubilizer component and/or *any* claimed %w/w of cilostazol, release modulator and/or solubilizer under *any* conditions (e.g., temperatures). The determination of at least 95 wt% cilostazol suspended in the composition under the specific conditions provided for in the Declaration fails to provide adequate written support to now narrow the claims to read upon the same degree of suspension of the active agent when the composition is not prepared under the same temperature conditions using the same agents, ratios and amounts of components. This newly added limitation represents a narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure and clearly is a concept that was not in Applicant's possession at the time of the invention.

Furthermore, for clarity of the record, though Dr. Giliyar alleges that the compositions exemplified in the Declaration were prepared in accordance with those presented in Example 2 of the instant specification, it is noted that Example 2 of the instant specification is directed to a single discrete example (i.e., 125 mg cilostazol, 572 mg d-alpha-tocopherol polyethylene glycol succinate, 64 mg d-alpha tocopherol succinate, and 52 mg polyethylene glycol) with a specific weight ratio of components that further contains polyethylene glycol, which was an element that was not included in any of the compositions studied by Dr. Giliyar. Accordingly, it is clear that none of the compositions presented in the Declaration of Dr. Giliyar are commensurate in scope with any of the claimed or exemplified in the specification or claims as originally filed. For these reasons, the Declaration of Dr. Giliyar fails to demonstrate that this assertedly "inherent" property of at least 95 wt% suspended cilostazol was a property present in the full breadth of embodiments presently claimed and, thus, it is properly concluded that the addition of the limitation "and at least 95 wt% of the cilostazol is suspended in the composition" introduces new matter into the claims.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of (1) a hydroxypropylmethylcelluose derivative as the release modulator (claim 35, 59 or 60); (2) glycerol monostearate as the release modulator (claim 35, 59 or 60); (3) at least 95 wt% of the cilostazol suspended in the composition (claim 35, 59 or 60).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35, 51-52, 54-56, 59-61, 65, 75-79 and 82 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Amselem et al. (U.S. Patent No. 5,891,469; 1999) in view of The Merck Index (Eleventh Edition, Monograph 2277, 1989; Pages 353-354), each already of record, for the reasons of record set forth at pages 11-14 of the previous Office Action dated May 2, 2007, of which said reasons are herein incorporated by reference.

Cancellation of claims 42-45 and 66-69 renders the instant rejection **moot** as applied to such claims.

Newly amended claims 35 and 59-60 remain properly included in the present rejection because (1) Amselem et al. clearly teaches the use of alpha-tocopherol polyethylene glycol succinate as the surfactant of the disclosed composition (col.5, l.49-66; which meets Applicant's use of alpha-TPGS as either the solubilizer and/or the release modulator, see, e.g., claim 35 and 59-60) and at least one dispersion adjuvant, e.g., tocopherol acetate, polyvinylpyrrolidone, a medium or long chain triglyceride

and/or polyethylene glycol (col.6, lines 23-26 and col.6, l.58-66; which also meets Applicant's use of these as solubilizing compounds or, as in the case of polyvinylpyrrolidone, a release modulator, see, e.g., claims 35 and 59-60), which clearly provides for Applicant's newly amended limitation(s) directed to the use of specific release modulating compounds; and (2) Amselem et al. teaches that the disclosed compositions are "solid, dry co-precipitates", which by virtue of the fact that the composition comprising the lipophilic substance, surfactant and dispersion adjuvant is itself a precipitate, is clearly indicative of 100 wt% of the lipophilic substance (which meets Applicant's newly added requirement of at least 95 wt% of the lipophilic substance to be "suspended" in the composition) "suspended" in the composition as a precipitate.

Further, newly amended claims 35 and 59-60 now require that the cilostazol be released "over an extended period of time" (see, e.g., claims 35 and 59-60). Applicant defines the phrase "extended period of time" as "release over an amount of time that exceeds the time required for immediate release" and further defines "immediate release" as "release of a drug at a rate which is not significantly modified by the method of drug formulation." Please see p.4-5 of the instant specification.

Figures 1 and 2 of Amselem et al. demonstrate that compositions formulated according to the disclosure release more than 60% of the lipophilic substance within the first 60 minutes of administration, depending upon the formulation used (note that 10 formulations were studied; see Legends of Figures 1 and 2). This meets Applicant's limitation directed to release of the active agent (i.e., in this case, cilostazol) "over an extended period of time" because neither the claims rejected herein nor the specification provide any quantification of the amount of time over which a particular amount of the active agent of the formulation is intended to be released such that it would have been clear as to what amount(s) of time and amount of active agent released would have been tolerated by the claims. Furthermore, Applicant defines the phrase "extended release" relative to the phrase "immediate release", but gives no indication as to what type or degree or rate of release is encompassed by the phrase

"immediate release" in view of the fact that "immediate release" is defined as "release of a drug at a rate which is not significantly modified by the method of drug formulation." Absent such an indication, it is herein noted that the length of time over which the formulations of Amselem et al. release the lipophilic agent meets this limitation, absent factual evidence to the contrary, and further absent some indication of the metes and bounds of the amount of active released over time intended by the term "extended release".

The term "extended release" permits some tolerance absent an explicit definition of the amount of time over which release of a particular amount of the active agent must occur. Where close prior art exists, the burden is on Applicant to establish that the term "extended release" is sufficiently clear to avoid such art. In the instant case, while Applicant has provided a definition of the term "extended release" at p.4-5 of the instant specification, the definition provides no indication or hint as to what amount of drug released over what amount of time constitutes infringement of the instant claims. There is nothing in the specification, prosecution history or prior art that provides any indication as to what amount of time over which release of the active agent must occur to be covered by the phrase "extended release". Absent such information, Applicant has not persuasively distinguished the instant claims over that of the prior art to Amselem et al.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Amselem et al. does not teach the delivery of cilostazol, or any other active agent, over an extended period of time. Applicant alleges that all of the release profiles of Amselem et al. show immediate release of the active agent and, thus, the reference fails to teach each and every element of the claims.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's remarks have been noted with regard to the interpretation of the phrase "released over an extended period of time" as recited in, e.g., claims 35 and 59-60, but are not persuasive. Applicant has

failed to provide any quantitation of the phrase "extended period of time" such that the specification and/or claims presently rejected sets forth the metes and bounds of what amounts of time over which the active agent may be released would be tolerated by the claimed invention. Though Applicant defines the term "extended period of time" relative to the term "immediate release" by stating that an "extended period of time" is "release over an amount of time that exceeds the time required for immediate release", Applicant gives no indication as to what degree of release is encompassed by the phrase "immediate release" such that one of skill in the art would be reasonably apprised of the distinction between the two terms. The definition of "immediate release" as providing "release of a drug at a rate which is not significantly modified by the method of drug formulation" provides no clarification on this issue.

In the absence of such disclosure, and further in view of the fact that Figures 1 and 2 of Amselem et al. demonstrate that compositions formulated according to the disclosure release more than 60% of the lipophilic substance within the first 60 minutes of administration, depending upon the formulation used (note that 10 formulations were studied; see Legends of Figures 1 and 2), Applicant has, respectfully, failed to patentably distinguish the instantly claimed composition over that disclosed by the prior art to Amselem et al. because (i) the instant claims fail to specify the length of time over which release of the active agent is effected and (ii) there is nothing of record to define what amount of time would be tolerated by the claims such that it would have been clear that the pharmaceutical preparations disclosed by Amselem et al., which provide, e.g., more than 60% release of the lipophilic substance within the first 60 minutes of administration, are excluded from and/or do not meet the instantly claimed invention.

For these reasons provided *supra*, and those previously made of record at pages 11-14 of the previous Office Action dated May 2, 2007, rejection of claims 35, 51-52, 54-56, 59-61, 65, 75-79 and 82 remains proper and is **maintained**.

Conclusion

Rejection of claims 35, 48-52, 54-61, 65 and 72-82 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

January 13, 2008

1/19/08
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER